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EXAMINER	
NGUYEN, TINA MY PHUONG	
ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,981	SCHAAF, HANSGEORG	
	Examiner	Art Unit	
	TINA NGUYEN	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 12/01/2009 has been entered. Claims 6-7 and 18 are canceled. Claims 1-5, 8-17, and 19 remain pending in the case.

2. The objection to the IDS has been withdrawn in light of applicant's explanation of where the document DE 2011886 is relevant in the specification. The objections to the specification have been withdrawn in light of applicant's amendments to the specification.

3. The previous 102/103 rejections have been withdrawn in light of applicant's amendments to the claims and applicant's certified translation of the foreign priority application 102004005709.5 (Germany).

4. New objections/ rejections are set forth as follows:

Specification

5. The disclosure is objected to because of the following informalities: on page 11, line 22, applicant refers to reference number "26" as being to an "optical system slider". However, applicant has already indicated this reference number as being the "shrink tube" on page 8, line 11. Furthermore, the optical system slider is not shown in the Drawings.

6. Appropriate clarification is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims **12, 15, and 17** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim **12** recites the limitation "the balloon" in line 4. There is insufficient antecedent basis for this limitation in the claim.

10. Claim **15** recites the limitation "the support tube" in line 2. There is insufficient antecedent basis for this limitation in the claim.

11. Claim **17** recites the limitation "the surgical implement" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims **1-5 and 9-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO93/15648) in view of Finn et al. (U.S. Patent 5,667,472) and Siegmund (U.S. Patent 4,479,612).

14. As to claim **1,** Wilk discloses an endoscope (Fig. 1) comprising a flexible catheter probe (14) having a plurality of lumens (page 7, lines 5-6), a handle (12) provided at the proximal end of the probe, an optical system (20) provided removably in at least one optical system lumen of the catheter probe (page 7, lines 8-10), at least one working lumen (52b) for a surgical instrument (wherein the working lumen is used to connect the suction devices, considered to be a surgical instrument because it is used in surgery) and a control element (40, 42) which is fixed to the distal end of the probe or in the

proximity thereof for bending the end of the probe and is guided movably in the axial direction at the probe (page 8, lines 13-14)

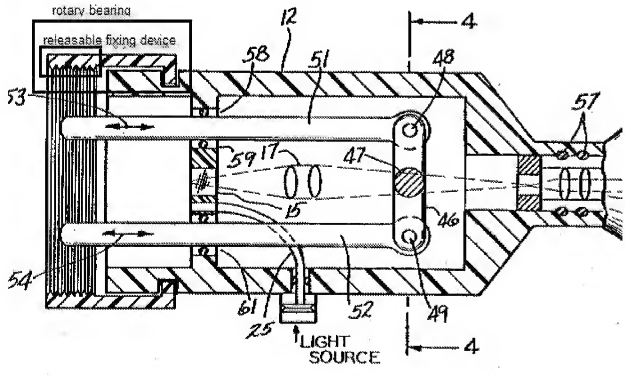
wherein:

the optical system which projects beyond the proximal end of the catheter probe (Fig. 1) is guided movably in a flexible tube (24, Fig. 3, page 7, lines 21-26); the tube is fixedly connected at a fixing location to the optical system (wherein that location is considered to be one point along the axial length of the optical fiber 22); the distal end of the optical system is pressed by the tube against a translucent cover (28, Fig. 3) which closes the distal end of the optical system lumen; the proximal end of the control element being releasably connected to a slider (44, Fig. 1) mounted to the handle (page 8, lines 8-17), and the catheter probe is a disposable element (page 9, lines 5-7).

15. Wilk does not disclose that the tube is elastically resilient in a longitudinal direction thereof. However, Finn discloses an analogous device which discloses optical fibers encased in a resilient tube (639, Fig. 21). It therefore would have been obvious to one of ordinary skill in the art to have Wilk's tube be made of a resilient type as the resiliency of the case would act to provide further protection to the fibers inside the sheath.

16. Wilk in view of Finn does not disclose that a rotary bearing is provided on the handle, where the catheter probe (at its proximal end) is mounted rotatably to the handle in the rotary bearing through which the control element (51 & 28) is displacebly guided with a releasable fixing device provided on the rotary bearing for the catheter probe.

17. Siegmund discloses an analogous device (Fig. 1) with a catheter probe (13) and handle (12). A rotary bearing (see Figure below) is provided on the handle. The probe is mounted rotatably to the handle in the rotary bearing (the probe is considered to be mounted rotatably to the handle because of the interactions of the two threads) through which a control element (28) is displaceably guided. Furthermore, a releasable fixing device for the catheter probe is provided on the rotary bearing (see Figure below, considered to be releasable because it allows fixing of the probe to handle while also allow its release).



18.

19. This connection is considered to be a quick and reliable operating connection (Col. 2, lines 42-47). It would have been obvious to one of ordinary skill in the art to substitute this type of connection for the connection disclosed in Wilk's modified

invention because it is a quick and reliable operating connection (as taught by Siegmund) and doing so would not predictably change the invention.

20. As to claim **2,** because Wilk's tube is connected along the entire length of the optical guide member (page 7, lines 21-26), it is also considered to be fixed at a proximal end of the tube.

21. As to claim **3,** Wilk discloses that a connecting portion (30 or middle of handle 12, Fig. 1) that is connectable to an illumination device and/or ocular (32) is provided at the proximal end of the optical system (Fig. 1).

22. As to claim **4,** Wilk does not specifically disclose that the fixing location is provided at the connecting portion. Wilk teaches that the sheath member contains a transmission element 26 and the optical fibers 22 which. In the handle 12, the transmission element 26 and the optical fibers 22 split, one going to connect to the CCD 30 and one connecting to the light source 36. Wilk does not teach that the tube 24 extends to the splitting part in the handle. However, it would have been obvious to one of ordinary skill in the art to extend the length of the member 24 until it reached the middle of handle 12, to where the split occurs, in order to allow further protection of the optical fibers and still arrive at predictable results.

23. As to claim **5,** Wilk discloses that the flexible tube is arranged outside the handle (Fig. 1, as the tube is inside of member 14 which is located outside of the handle 12).

24. As to claim **9,** Siegmund discloses that the control element is passed through the fixing device (Fig. 1).

25. As to claim **10,** Siegmund discloses that the proximal end of the control element is passed through the fixing device (Fig. 2).

26. Claim **8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO93/15648) in view of Finn et al. (U.S. Patent 5,66,472) and Siegmund (U.S. Patent 4,919,112) as applied to claim 1, further in view of DeGuillebon (U.S. Patent 6,595, 984).

27. Wilk in view of Finn and Siegmund does not disclose that the rotary bearing has a manually actuable rotary portion which is non-rotatably connected to the catheter probe.

28. DeGuillebon discloses an analogous device with a separable handle (12) and probe (18, Fig. 1). A rotary bearing (28) is provided on the handle (Col. 5, lines 22-23, Fig. 2) and at its proximal end, a probe is mounted rotatably to the handle in the bearing (considered to be mounted rotatably because mounting of the probe requires a rotating of bearing 28). The bearing further comprises a releasable fixing device (the conical portion 46, Fig. 2 which is tightened and grasps the probe 18 when tightened) and has a portion which is non-rotatably connected to the probe (52, wherein the ball falls into detent 40 of probe 18 to allow additional sheath securing means, Col. 5, lines 15-16, Fig. 2). DeGuillebon's connection allows for a connection in which the probe is "readily and more securely held" (Col. 7, lines 29-31). It therefore would have been obvious to one of ordinary skill in the art to substitute DeGuillebon's connection for the connection disclosed by Wilk's modified device for the advantages taught by DeGuillebon, as noted above.

29. Claim **17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO93/15648) in view of Finn et al. (U.S. Patent 5,667,472) and Siegmund (U.S. Patent 4,919,112) as applied to claim 1, further in view of Takamatsu (U.S. Patent 4,487,489).

30. Wilk in view of Finn and Siegmund does not disclose a surgical implement is removable from the working lumen. However, Takamatsu shows that probes are known in the art to contain removable surgical instruments in lumens (Fig. 1). It therefore would have been obvious to one of ordinary skill in the art to modify Wilk's device to contain a lumen and a removable surgical instrument placed in that lumen in order to allow the operator the ability to operate on the patient with that instrument through the probe.

31. Claim **19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO93/15648) in view of Finn et al. (U.S. Patent 5,667,472) and Siegmund (U.S. Patent 4,919,112) as applied to claim 1, further in view of Strong (U.S. patent 6,083,152).

32. Wilk in view of Siegmund does not disclose that the catheter probe is an injection molded component or an extruded component. However, this is a method limitation which does not seem to inherently affect the structure of the device. Strong discloses a probe which is made of an extruded component (Abstract). Because Wilk in view of Siegmund discloses a device with the claimed limitation, it would have been obvious to one of ordinary skill in the art to extrude Wilk's catheter probe since sheaths have been known in the art to be extruded and still predictably arrive at the same working invention.

33. Claims **11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO93/15648) in view of Finn et al. (U.S. Patent 5,667,472) and Siegmund (U.S. Patent 4,919,112) as applied to claim 1, further in view of Ebling et al. (U.S. Patent 5,569,161) and Samson et al. (U.S. Patent 5,090,959).

34. As to claim **11,** Wilk in view of Siegmund does not disclose that the catheter has a balloon to which a dilation medium can be fed by way of a balloon lumen in the catheter probe.

35. Samson discloses an analogous device in which a catheter probe (13, Fig. 1, Col. 2, lines 7-15) having a balloon (26) inflatable by a balloon lumen (18, 19, Col. 3, lines 11-13). Ebling discloses an analogous device (Fig. 9) in which a balloon is inflated in order to be able to perform an operation of dislodging/ breaking up an occlusion (Col. 9, lines 8-9). It therefore would have been obvious to one of ordinary skill in the art to modify Wilk's device to have a balloon on the catheter and to use one of the lumens as a balloon lumen in order to give Wilk's device the ability to break up occlusions in certain procedures.

36. As to claim **12,** Wilk in view of Siegmund does not specifically disclose a guide wire lumen. Samson discloses a guidewire lumen (where 86 is inserted, Fig. 1) which extends from the distal end of the probe to an exit opening in the catheter (52), the exit opening behind the balloon. Samson discloses that the guidewire can help the guidance of the probe into the tissue (Col. 4, lines 34-41). It therefore would have been obvious to one of ordinary skill in the art to use one of Wilk's lumens to accommodate a guidewire for the advantage disclosed by Samson, as noted above.

37. Claims **13-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO93/15648) in view of Finn et al. (U.S. Patent 5,667,472) and Siegmund (U.S. Patent 4,919,112) as applied to claim 9, further in view of Shockey (U.S. Patent 5,168,864).

38. As to claim **13,** Wilk in view of Siegmund does not disclose that the control element is arranged in a flexible support tube which is arranged in a control lumen of the catheter probe and terminates at a given spacing from the distal end of the probe, wherein the given spacing corresponds approximately to the length of a distal portion of the probe, which is to be bent over by the control element.

39. Shockey discloses a deflectable probe (10, Fig. 1) in which the deflecting motion is actuated by a control element (24) supported by a flexible support tube (20). The tube is arranged in a control lumen (22) of the probe and terminates at a given spacing from the distal end of the probe, wherein the given space (D1, Figs. 2-3) corresponds approximately to the length of a distal portion o f the probe which is bent over by the control element (Col. 4, lines 34-42). The length of the support member inserted into the probe is adjustable by valve (21, Fig. 1) and therefore the support member allows the "physician to selectively adjust and adapt the radius R of the flexible tip portion" (Col. 4, lines 59-62). It therefore would have been obvious to one of ordinary skill in the art to modify Wilk's control elements to consist of the adjustable support member and valve as disclosed by Shockey in order to have the advantages taught by Shockey, as noted above.

40. As to claim **14,** Wilk in view of Siegmund does not specifically disclose how the control element is fixed to the distal end of the catheter probe. Shockey discloses an analogous device in which a control element is fixed to the distal end of a probe by an adhesive (Col. 4, lines 7-8). One of ordinary skill in the art would appreciate that in order for the proper functioning of the invention, the control element would need to be fixed to the distal end of the probe and that the method of fixing does not matter. It therefore would have been obvious to one of ordinary skill in the art to use this type of fixation disclosed by Shockey to fix the control element and still predictably arrive at the same working invention.

41. As to claim **15,** Shockey discloses that the support tube is fixed at a fixing location in the axial direction (wherein the tube is fixed at point 21, Fig. 1, when the clamp is closed). The remaining portion of the support tube is considered to be movable with respect to the inside wall of the control lumen because the support tube is not fixedly attached to the control lumen.

42. As to claim **16,** Shockey discloses, in another embodiment, that there are two tubes that offer support to the control element. Tube 64 is axially movable, controlled by clamp 68, and tube 60, which is fixedly received within the lumen 63 (Col. 5, lines 13-16). In order to be fixedly received, the tube has to be fixed at some fixing location. Although Shockey is silent as to the exact fixing location of the first tube, one of ordinary skill in the art would appreciate that in order for the proper functioning of the invention, the tube would just need to be fixed at a location and the exact location of the fixing does not matter. Therefore, it would have been obvious to one of ordinary skill in the art

to fix the tube at the distal end of the support tube and still arrive at the same predictable endoscope.

Response to Arguments

43. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

44. Applicant's new claim amendment made to independent claim 1 has been addressed in the above rejection.

Conclusion

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kishi (U.S. Patent 4,779,612) discloses an endoscope capable of deflection of the distal end and rotation between handle/ shaft. Hussein (U.S. Patent 4,762,120) discloses endoscope with a rotatable connection between the shaft and handle.

46. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TINA NGUYEN whose telephone number is (571)270-1489. The examiner can normally be reached on M-Thurs 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./
Examiner, Art Unit 3739
2/26/2010

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739